PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/EP2005/002261	International filing date *(day/month/year)* 03.03.2005
Priority date *(day/month/year)* 03.03.2004	
International Patent Classification (IPC) or both national classification and IPC A61K9/70, B01J13/00, A61L15/44	
Applicant SWITCH BIOTECH AG	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Villa Riva, A

Telephone No. +49 89 2399-8404

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-39
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-39
Industrial applicability (IA)	Yes:	Claims	1-39
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V

The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: DE 199 40 241 A, disclosing the use of ink-jet printing technology for distributing active agents on the surface of a substrate;
D2: WO 91/19480 A, disclosing wound healing materials comprising a freeze-dried gel and an active agent;
D3: US 6 117 437 A , disclosing a medicated sheet for wound treatment with an active substance homogeneously dispersed therein
D4: Eun Jeong Cho et al: Analytical Chemistry, vol. 74, no. 24,(2002), pages 6177-6184, discosing the application of pin printing technology to obtain biosensor arrays on xerogels
D5: US 2002/127254 A1, disclosing cosmetic or therapeutic active agents delivered by gel discs which dissolve in contact with the skin or a wetting solution;

Unless otherwise indicated, reference is made to the relevant passages emphasized in the Search Report.

None of the cited prior art items dicloses exactly the same process and compositions of the present application, which can, therefore, be considered novel under Art. 33(1) and (2) PCT.

In D1, surface application of the active agents by printing is described as an improvement over homogeneously mixing the active agents into the matrix. The latter method could give rise to undesired effects like incompatibility phenomena between active agent and excipients or between two different active agents for combination therapy etc.. The difference with respect to the process of the present application is that no freeze or vacuum drying is foreseen. After applying the active agent, the substrate is dried by an air flow.
D2, which is considered the closest prior art, discloses the advantages of freeze-drying of the preparations for wound treatment in terms of storage, stability of the active principle, patient compliance. In D2 the active ingredient is homogeneously mixed into the matrix of

the gel.
The problem is to obtain a sheet or gel for the release of active agents with good release and optimal stability, compatibility and storage properties.
It would be obvious for the skilled person to combine the two methods in order to exploit the advantages of printing and of freeze-drying. Sterilization of the materials is a routine step to be undertaken when wounds (especially e.g. burns) are treated.
In summary, the subject-matter of present claims 1-39 is considered to lack inventive step under Art. 33(1) and (3) PCT.

Section VIII

The wording of present claims 1 and 2 appears to be identical and therefore redundant.
The dependency of claims 32-37 from claim 23 leads to an inconsistency as far as the category is concerned, since claim 23 does not relate to a method (Art. 6 PCT).